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EXAMINER	
LANDAU, SHARMILA GOLLAMUDI	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
11/06/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/913,752	FERCEJ TEMELJOTOV ET AL.	
	Examiner	Art Unit	
	Sharmila Gollamudi Landau	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65 and 70-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65, 70-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 8/23/07 is acknowledged. Claims 1-64 and 66-69 stand cancelled. Claims **65, 70-83** are pending in this application.

Response to Arguments

Applicant argues that Briskin fails to appreciate the significance of forming a matrix with these components to facilitate the controlled release of clarithromycin. Applicant argues that although Briskin teaches a composition comprising clarithromycin, hydroxymethylcellulose, and glycerol behenate, Briskin fails to "appreciate" the significance of forming a matrix with these components. Applicant argues that Briskin teaches glyceryl behenate as an extrusion aid Applicant argues that the prior art fails to teach a matrix comprising "about" 13-18% hydroxymethylcellulose. Applicant argues that Gibson fails to remedy the deficiencies of Briskin because Gibson does not suggest a matrix formulation utilizing glyceryl behenate and hydroxypropyl methylcellulose in the amounts specified in new claim 82. Applicant argues that in KSR, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination.

Applicant's arguments filed 8/23/07 have been fully considered but they are not persuasive. The claims are directed to a pharmaceutical composition and method of making a pharmaceutical composition comprising about 10-36% glycerol behenate; about 13-18% hydroxypropyl methylcellulose, dispersed within the matrix, and at least about 42% clarithromycin dispersed within a matrix. Briskin discloses an oral composition containing 43.4% clarithromycin, 5.5% povidone, 26% carbopol, 5% hydroxypropylcellulose (an alkyl-

substituted cellulose ether), 10% glyceryl behenate, and 10% microcrystalline cellulose. See table 1 on page 8.

Firstly, it is noted that applicant's argues that Briskin does not teach a matrix; however the examiner disagrees. The examiner points out that instant application discloses on page 7 that the instant invention is made by mixing all the ingredients together, sieving, and compressing to form a tablet. The examiner points out that Briskin discloses on page 6, the method of making the tablet wherein the *all* the ingredients are blended thoroughly, granulated, and then the particles are formed into tablets. Thus, Briskin teaches combing all the components, which form a matrix.

Secondly, Briskin utilizes the same fatty component, glyceryl behenate, in the same claimed amount. Thus, the fact that the prior art utilizes glyceryl behenate for a different reason does not provide patentability to the instant invention. It should be noted that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues that Briskin fails to provide a motivation to use hydrophilic polymers in conjunction with fatty components.

The examiner points out that Briskin clearly discloses the use of hydrophilic binders such as hydroxypropylcellulose and polyvinylpyrrolidone in combination with glyceryl behenate. Further, the examples utilize 5.5% PVP and 5% HMC. Therefore, with regard to the concentration, it is the examiner's position that 10.5% renders about 13% obvious.

Applicant argues that Gibson and Evenstad do not remedy the deficiencies of Briskin. Applicant argues there is no motivation to experiment with hydrophilic polymers as fatty components to provide a matrix. Applicant argues the examiner has relied upon impermissible hindsight.

The examiner has discussed the merits of Briskin above. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Firstly, the examiner points out that the Briskin discloses the use of a hydrophilic polymer, in particular hydroxypropylcellulose (HPC), in combination with a fatty component. Additionally, Briskin discloses the use of various hydrophilic binders including HPC to retard release. Therefore, Gibson is only relied upon to teach the functional equivalency of PVP, HPC, and HPMC as hydrophilic polymers since the Briskin document itself suggests the combination of a hydrophilic polymer and a fatty component. Applicant has not addressed this argument. With regard to Evenstad, Briskin teaches the use of a hydrophilic binder and Evenstad teaches that low viscosity HPMC are used if the purpose is to utilize HPMC as a binder. Therefore, the examiner has made a reasonable motivation to specifically utilize a low viscosity cellulose polymer and applicant has not addressed this.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As discussed above, Gibson is only relied upon to teach the instant hydrophilic polymer. Briskin is not deficient in the disclosure of a matrix formulation utilizing glyceryl behenate and a hydrophilic substance. Thus, neither Gibson nor Evenstad need to teach clarithromycin or glyceryl behenate.

With regard to applicant's argument pertaining to KSR, the examiner points out that the rejection is not based on combining elements. Rather, as discussed above, Briskin teaches the hydrophilic component combined with the glyceryl behenate. The premise of the rejection is substituting functional equivalents, which applicant has yet to address.

Therefore, it is the examiner's position that Briskin in view of Gibson renders the instant invention obvious.

Claim Rejections - 35 USC § 112

The rejection of claim 79 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's amendments filed 8/23/07.

The rejection of claim 79 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments filed 8/23/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 61-63, 65-66, 68, 72, 76-77 under 35 U.S.C. 102(b) as being anticipated by US patent 5,707,646 to Yajima et al is withdrawn in light of applicant's amendments filed 8/23/07.

The rejection of claims 61-68, 76-78, 80-81 under 35 U.S.C. 102(b) as being anticipated by WO 95/22319 to Briskin et al is withdrawn in light of applicant's amendments filed 8/23/07.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 65, 72-73, 76-78, 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22319 to Briskin et al in view of Gibson et al (5,811,120).

Briskin teaches preparing pharmaceutical composition comprising up to 90% of an active agent, 1-75% of an extrusion aid including glyceryl behenate, hydrogenated vegetable oil, fats, fatty acid esters, fatty acids, etc. The composition further contains binding agents including polyvinylpyrrolidone (povidone K90), carboxymethylcellulose, and hydroxymethylcellulose (HMC) to retard release. See page 4-5. Briskin teaches an oral composition containing 43.4% clarithromycin, 5.5% povidone, 26% carbopol, 5% hydroxypropyl cellulose (an alkyl-substituted cellulose ether), 10% glyceryl behenate, and 10% microcrystalline cellulose. See table 1 on page 8. Specifically example 1b. Note that example 1b contains 5.5% povidone and 5% hydroxypropylmethylcellulose, which comprises a total of 10.5% of the binder.

The composition is then formulated in to a tablet or capsule. See page 7, line 7. On page 6, the method of making the tablet is disclosed wherein the *all* the ingredients are blended thoroughly, granulated, and then the particles are formed into tablets. Briskin discloses on page 5, lines 34-35 an enteric coating. Note that enteric coating is inherently acid resistant coating.

Regarding claim, 65, since the prior art discloses the same components (a fatty component, a hydrophilic component, and clarithromycin), it is the examiner's position that the functional limitation of claim 65 are inherent. The examiner has provided a reasonable rationale for inherency and thus the burden has shifted to applicant to provide evidence to the contrary. Note MPEP 2112.

Briskin teaches the use of hydrophilic binders, specifically HMC and PVP (povidone) as the hydrophilic binder, however Briskin does not the use of hydroxypropylmethylcellulose (HPMC). Further, Briskin does not teach instant surfactant.

Gibson et al teach pharmaceutical formulations containing raloxifene. Gibson et al teaches the conventional additives in pharmaceutical formulations such as hydrophilic binders. Gibson teaches the term "hydrophilic binder" represents binders *commonly used in the formulation of pharmaceuticals*, such as ***polyvinylpyrrolidone (PVP)***, polyethylene glycol, sucrose, dextrose, corn syrup, polysaccharides (including acacia, tragacanth, guar, and alginates), gelatin, and cellulose derivatives (including ***hydroxypropyl methylcellulose, hydroxypropyl cellulose***, and sodium carboxymethylcellulose). See column 3, lines 50-60. Further, Gibson teaches the use of surfactants including sodium docosate. See column 3, lines 60-67. Further, the reference teaches that the preparation of the oral formulations is well known in the art such as direct compression. The process includes mixing the active with the hydrophilic binder and surfactant, which is then, milled if necessary, drying the granules, and compressing into tablets (col. 5, lines 10-15).

It would have been obvious of one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin et al and Gibson et al and utilize the instant hydrophilic binder (HPMC). One would have been motivated to substitute Briskin's hydrophilic binders (cellulose derivative HMC and Povidone) for instant cellulose derivative (HPMC) with a reasonable expectation of similar results since Gibson teaches that HPMC, HMC and Povidone are conventional hydrophilic binders utilized in pharmaceutical compositions. Therefore, it is prima facie obvious for a skilled artisan to substitute one functional equivalent with another

known functional equivalent with the expectation of similar results and success since the art establishes that both are hydrophilic and act as binders in the composition. The examiner points out that Briskin teaches the binder in a total weight percent of 10.5 (5.5% povidone and 5% hydroxypropylmethylcellulose). Thus, it is the examiner's position that the prior art's 10.5% reads on the claimed "***about*** 13%". It is noted that the term "about" is not defined in the specification to mean exactly. See MPEP 2111.01. Moreover, it is within the skill of an artisan to manipulate the amount of the binder, which is taught to retard the release in the composition. One would have been motivated to do so depending on the desired release rate.

Additionally, Gibson teaches the conventional use of surfactants such as instant sodium docusate in pharmaceutical compositions. Thus, the use of conventional additives in the preparation of pharmaceuticals is prima facie obvious.

Claims 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22319 to Briskin et al in view of Gibson et al (5,811,120) in further view of Evenstad et al (5,126,145).

The disclosure of Briskin and Gibson have been set forth above. Briskin teaches the use of HPC and PVP as the hydrophilic *binder* and Gibson teaches the use of PVP, HPC or HPMC as the hydrophilic *binder*.

The references do not specify the viscosity of HPMC.

Evenstad teaches a controlled release tablet. Evenstad teaches the use of high viscosity HPMC to provide sustain release whereas a water-soluble pharmaceutical binder such as HPMC having binding properties has a much lower viscosity; typically a viscosity of less than 100 cps

such as METHOCEL E15. See column 3, lines 5-67. METHOCEL E15 has a viscosity of 12-18 cps.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin, Gibson, and Evenstad and specifically utilize a low viscosity HPMC. One would have been motivated to do so since Evenstad teaches high viscosity HPMC is useful for its sustaining action and low viscosity HPMC is useful for its binding properties. Therefore, a skilled artisan would have been motivated to utilize a low viscosity HPMC with a reasonable expectation of similar results since both Briskin and Gibson teach the use of the cellulose derivative for its binding property and Evenstad teaches the low viscosity cellulose derivative provide this function.

Claims 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22319 to Briskin et al in view Gibson et al (5,811,120) in further view of Curatolo et al (5,605,889).

The disclosures of Briskin and Gibson have been set forth above.

Although, Briskin teaches the use of conventional excipients in the composition, Briskin does not teach the use of the instant phosphate buffer.

Curatolo teaches azithromycin compositions. Curatolo teaches in addition to the active ingredient azithromycin, the tablets may be formulated with a variety of *conventional excipients* such as binders, flavorings, buffers, diluents, colors, lubricants, sweetening agents, thickening agents, and glidants. See column 6, lines 55-66. Curatolo teaches a powder composition used to make suspensions may also contain conventional optional ingredients such as a buffer to maintain a high pH upon reconstitution. Suitable buffers and pH-altering agents include

anhydrous tribasic sodium phosphate, anhydrous sodium carbonate, glycine, and the like. See column 8, line 60 to column 9, line 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin and Curatolo and utilize conventional excipients such as buffers. One would have been motivated to do so since the use of conventional additives such as buffers are routinely utilized in the art for maintaining the pH of a composition as taught by Curatolo. Thus, a skilled artisan would have been motivated to utilize a buffer to maintain the desired pH of the composition.

Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22319 to Briskin et al in view Gibson et al (5,811,120) in further view of Khan et al (5,656,296).

The disclosures of Briskin and Gibson have been set forth above.

Briskin teaches the composition may be coated with an enteric coating or other coatings. See page 5, lines 30-35.

The combined references do not teach a coating comprising the instant polymers.

Khan teaches a dual control sustained release drug delivery system. Khan teaches the delivery system is coated with a coating layer comprising a water insoluble polymer and water-soluble film forming polymers including cellulose derivatives such as hydroxypropylcellulose, hydroxypropyl-methylcellulose, hydroxypropylmethylcellulose phthalate, sodium carboxymethylcellulose, and the like, and mixtures thereof. See column 6, lines 30-60.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin, Gibson, and Khan and utilize a coating layer

comprising a mixture of polymers such as HPMC and HPC. One would have been motivated to do so to provide a sustained release effect. Further, a skilled artisan would have reasonably expected success since Briskin teaches the use of various coating layer.

Claims 65, 70-72, 76-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/42311 to Akiyama et al in view WO 98/14176 to Farah et al (US equivalent 6,194,005 is used as the translation). It should also be noted that applicant has not perfected priority.

Akiyama et al teach a gastrointestinal mucosa adherent matrix adapted to stay long in the gastrointestinal tract for sustained drug release. The gastrointestinal mucosa-adherent matrix which is solid at ambient temperature includes a matrix in which each matrix particle containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient has a coating layer comprising or containing the viscogenic agent.

Examples of viscogenic agent include polymers containing carboxyl groups or salts thereof, cellulose ethers, polyethylene glycols having molecular weights not less than 200,000, and naturally-occurring mucous substances. The preferable viscogenic agents are those having a viscosity in the range of 3 to 50,000 cps, preferably 10 to 30,000 cps, and more preferably 15 to 30,000 cps as a 2 percent by weight aqueous solution thereof at 20.degree. C. Cellulose ethers taught include hydroxymethylcellulose. See page 17, lines 10-35 and page 18, line 36. The viscogneic agent is taught in a preferable amount of 1-20%. See page 19, lines 10-15.

The matrix may be made of polyglycerol fatty acid ester be about 15 to 80.degree. C., preferably about 30 to 75.degree. C. and more preferably about 45 to 75.degree. C or lipids having a melting point of 40 to 120.degree. C., preferably 40 to 90.degree. C. The polyglycerol

fatty acid esters include behenyl glycerides and the lipids include glycerol fatty acid esters. See page 8, lines 1-5, page 10, and page 12, lines 8-36 .The lipid is utilized in an amount of 5-98%.

The active includes antimicrobial substance and preferably clarithromycin. See page 14, lines 25-30 and page 15, lines 1-2. the active is used in an amount of 0.005-95% and preferably about 10- to about 50%. See page 26, lines 12-20.

The solid composition may be coated with a coating material including hydroxypropylmethylcellulose phthalate. See page 22, lines 15-25 and page 23, lines 30-35. The solid dosage form includes tablets. See page 25, line 14. The composition includes surfactants. See page 29, lines 1-15. The examples provide the method of making the composition.

Akiyama does not specify the glycerol fatty acid ester.

Farah teaches a method for preparing a pharmaceutical composition with modified release of the active principle, comprising a matrix as lipid matrix agent, of an ester of behenic acid and of alcohol. The alcohol is advantageously chosen from the group comprising **glycerol, polyglycerol,** propylene glycol, propylene glycol in combination with ethylene oxide and polyethylene glycol. These matrix agents exhibit the advantage of having a melting point of greater than 50.degree. C., which prevents them from disintegrating at the compression temperature. Furthermore, this melting point is greater than the internal temperature of the human body (37.degree. C.), which allows the lipid agent to have a more pronounced matrix behavior. The lipid is used in an amount of 1-15%. See column 4, lines 10-55. Glycerol behenate is the preferred lipid for the matrix.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Akiyama and Farah and utilize glycerol behenate in

Akiyama's composition. One would have been motivated to do so with a reasonable expectation of success and similar results since Akiyama teaches the use of lipids with a melting point of 40-120 degrees C such as glycerol fatty acid esters for the matrix and Farah teaches glycerol behenate may be used to form a lipid matrix in sustained release composition. Further, Farah teaches the esters of behenic acid and alcohol may used wherein the alcohol may be glycerol or polyglycerol. Thus, Farah teaches that both the polyglycerols of fatty acid esters and glycerol of fatty acid esters may be used to form the matrix and therefore establishes the functional equivalency. Therefore, it would have been obvious to substitute one lipid matrix forming material with another similar lipid matrix forming material.

Claims 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/42311 to Akiyama et al in view WO 98/14176 to Farah et al (US equivalent 6,194,005 is used as the translation) in further view of Curatolo et al (5,605,889).

The disclosures of Akiyama and Farah have been set forth above.

Although, Akiyama teaches the use of conventional excipients in the composition, Akiyama does not teach the use of the instant phosphate buffer.

Curatolo teaches azithromycin compositions. Curatolo teaches in addition to the active ingredient azithromycin, the tablets may be formulated with a variety of *conventional excipients* such as binders, flavorings, buffers, diluents, colors, lubricants, sweetening agents, thickening agents, and glidants. See column 6, lines 55-66. Curatolo teaches a powder composition used to make suspensions may also contain conventional optional ingredients such as a buffer to maintain a high pH upon reconstitution. Suitable buffers and pH-altering agents include

anhydrous tribasic sodium phosphate, anhydrous sodium carbonate, glycine, and the like. See column 8, line 60 to column 9, line 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize conventional excipients such as buffers. One would have been motivated to do so since the use of conventional additives such as buffers are routinely utilized in the art for maintaining the pH of a composition as taught by Curatolo. Thus, a skilled artisan would have been motivated to utilize a buffer to maintain the desired pH of the composition.

Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/42311 to Akiyama et al in view WO 98/14176 to Farah et al (US equivalent 6,194,005 is used as the translation) in further view of Gibson et al (5,811,120).

The disclosures of Akiyama and Farah have been set forth above.

Although, Akiyama teaches the use of surfactants including polyoxyethylene sorbitan fatty acid esters, ethoxylated castor oil, sodium lauryl sulfate, Akiyama does not teach the instant surfactant.

Gibson et al teach pharmaceutical formulations containing raloxifene. Gibson et al teaches the conventional additives in pharmaceutical formulations such as surfactants. Gibson teaches the term "surfactant", represents ionic and nonionic surfactants or wetting agents commonly used in the formulation of pharmaceuticals, such as ethoxylated castor oil, polyglycolyzed glycerides, sorbitan fatty acid esters, polyoxyethylene sorbitan fatty acid esters, sodium docusate, sodium laurylsulfate, cholic acid or derivatives thereof, lecithins, and phospholipids, etc.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize the instant surfactant. One would have been motivated to do so with a reasonable expectation of success and similar results since Akiyama teaches the use of anionic surfactants in the composition and Gibson teaches the instant surfactant is a routine anionic surfactant used in the pharmaceutical art and is functionally equivalent to sodium lauryl sulfate which is taught by Akiyama.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila Gollamudi Landau
Primary Examiner
AU 1616